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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,883	11/21/2000	Susana Salceda	DEX-0115	2018

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,883

Applicant(s)

SALCEDA ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-16-2003 has been entered.

Claims 3-7 are pending and examined on merits.

Claim Rejections - 35 USC § 112

Rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the instant claims no longer recite the rejected limitation.

Rejection of the claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because the instant claims are limited to SEQ ID NO:1.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

Claims 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are interpreted as drawn to method for determination whether cancer is metastasized or not based on an expression level of SEQ ID NO:1. The specification at page 19-24 teaches that instant SEQ ID NO:1 is overexpressed in ovarian cancer and some other cancers as compared to normal tissue. However, neither the specification nor any art of record teaches a relationship between metastatic capacity of a cancer and expression of instant SEQ ID NO:1. Assays for human cancer cell invasion and metastasis are known in the art (see Frandsen et al., Fibrinolysis, 1992:6, Suppl 4:71-76). However, the specification does not present any data on a relationship between SEQ ID NO:1 and metastatic potential of a cancer. Hill (The Basic Science of Oncology, Tannock et al., Eds, McGraw Hill, NY, 1992, pp 178-195) specifically teaches that primary tumors contain populations of cells with different metastatic abilities. The development of metastatic potential may be viewed as one of the late states of a process that has been in progress since the initiation of the tumor and that results in the evolution of populations of tumor cells which become more growth autonomous and malignant, thus determination of metastatic potential is dependent upon stage of tumor development and metastasis involves complexity of the processes and it is particularly difficult to distinguish tumors that are likely to metastasize (see the Summary at p. 193). Further, conventional assays of metastatic capacity test not only invasive properties, but also properties of the ability of cells to invade into and out of blood vessels, to survive in circulation, to arrest and to grow at a new site, for example, metastatic capacity is tested in model systems such as

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chorioallantoic membranes in chicken eggs. A small window is made in the shell of the eggs, sample cells are introduced to the membrane, invasion of the cells across membrane is observed microscopically and the formation of metastases in organs of the chick embryo can be quantitated (Hill, cited supra, p. 184, para 4). Without further guidance or exemplification on expression of SEQ ID NO:1 on metastatic capacity of tumors, the use of a method for determining metastatic capacity of a tumor comprising determining an expression level of SEQ ID NO:1 in a biological sample wherein the presence of SEQ ID NO:1 is characteristic of an invasive and metastatic capacity of cancer would be highly unpredictable since the specification has not been demonstrated what kinds of SEQ ID NO:1 expression (over, and/or under) is indicator of metastasis of cancer. The specification fails to provide sufficient guidance to enable one skilled in the art to use the claimed method. In view of the unpredictability in the art pertaining to SEQ ID NO:1 expression level on metastasis of any cancer and that a relationship between metastasis of a cancer and altered expression of SEQ ID NO:1 is not known in the art as discussed above as well as the lack of sufficient guidance in the specification, one skilled in the art would be forced into undue experimentation in order to use the invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are interpreted as drawn to method of staging cancer by using

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the level of SEQ ID NO:1. The teaching of the specification that that SEQ ID NO:1 is overexpressed in ovarian cancers and some other cancers is not enough for the claimed invention because Novak et al (1975, Novak's Textbook of Gynecology, Chapter 23, pages 480-1 only) teach staging a cancer is not a trivial matter at page 481 in that staging (stage I-IV) of ovarian cancer involves several different considerations. Neither the instant specification nor any art of record teaches in what amount of SEQ ID NO:1 detection would be indicative of for example, Stage II vs Stage IV of an ovarian cancer. Considering limited guidance in the specification and unpredictability in the art using SEQ ID NO:1 as staging marker of a cancer, it is concluded that undue experimentation is required for one skilled in art to practice the invention.

Allowable Subject Matter

Claim 3 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
June 25, 2003



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600